

REMARKS

The applicants have studied the Notice of Non-Compliant Amendment dated June 12, 2003, and re-submit the Amendment previously filed June 2, 2003 with a complete listing of all of the claims as requested. Reconsideration and allowance of all the claims in view of the above amendments and following remarks are respectfully requested.

The applicants have studied the Office Action dated February 28, 2003, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 56, 65, 74, and 84 have been amended; thus, claims 56-95 are pending. Consideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

The Examiner indicated that the Information Disclosure Statement (IDS) filed August 13, 2002 failed to comply with 37 CFR 1.98(a)(2), and in particular, that the Examiner did not have copies of the documents listed under "Other Documents" in the IDS. However, enclosed are copies of the IDS dated August 2, 2002 and the return postcard indicating the Patent Office's receipt on August 13, 2002 of the IDS and 91 references, which include the documents listed under "Other Documents" in the IDS. Thus, the applicants respectfully submit that the IDS filed August 13, 2002 was in compliance with 37 CFR 1.98(a)(2). Further, the applicants respectfully point out that copies of all the documents listed under "Other Documents" are also available for the Examiner's consideration in this application's parent case, U.S. Patent Application Serial No. 09/466,006 filed December 17, 1999, now U.S. Patent No. 6,551,276 issued April 22, 2003.

Claims 84-95 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Examiner indicated that claims 84-95 appear to claim an infusion system as well as a method. However, the applicants point out that claims 84-95 recite "a method of estimating a bolus amount of fluid to be infused into the body," which is intended for use "[i]n an infusion

system....” Thus, claims 84-95 claim a method, not an infusion system. The applicants respectfully submit that claims 84-95 are not indefinite. Accordingly, withdrawal of the rejection of claims 84-95 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 56-83 were rejected under 35 U.S.C. § 102(b) as being anticipated by Worthington et al. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an infusion system including a bolus estimator or a method of estimating a bolus for an infusion system. The bolus estimator or method utilizes externally supplied values to estimate an amount of fluid to be infused into a body based upon an estimate of a material to be ingested by the body. The bolus estimator also interfaces with a programmer that includes at least one button and at least one display including at least one touch screen element. The externally supplied values and the estimate of the material to be ingested by the body are input into the programmer using either the at least one button or the at least one touch screen element, and then an estimate of the amount of fluid to be infused is calculated.

Claim 56 recites “a bolus estimator that utilizes externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body” (emphasis added). Claim 65 also recites “providing a programmer for interfacing with externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body” (emphasis added). Claim 74 similarly recites “interfacing means providing a programmer for interfacing with externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body” (emphasis added). The applicants respectfully submit that the Worthington et al. reference does not disclose, teach, or suggest an infusion system including a bolus estimator, or a method of estimating a bolus for an infusion system, which utilizes or interfaces with externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body, as recited in the claims.

The Worthington et al. reference is directed to a diabetes management system for predicting a future blood glucose value of a patient and for recommending a corrective action to the patient when the future blood glucose value lies outside of a target range. For example, if the system calculates a future blood glucose value that lies above a hyperglycemic value, the system suggests a supplemental insulin dose for the patient. Alternatively, if the system calculates a future blood glucose value that lies below a hypoglycemic value, the system alerts the patient that he/she is likely to develop hypoglycemia unless a carbohydrate supplement is taken, and then recommends a number of grams of carbohydrates to be consumed by the patient to avoid developing hypoglycemia. However, the system described in the Worthington et al. reference does not estimate an amount of fluid or insulin to be infused into the patient based upon an estimate of a material to be ingested by the body, such as an estimated number of carbohydrates or amount of food to be consumed by the patient, as in the claimed embodiments.

Claims 56, 65, and 74 have been amended, not for reasons of patentability, but merely to clarify that such an estimate of a material to be ingested by the body is input into a programmer, and then externally supplied values are utilized to estimate the amount of fluid to be infused based upon the inputted estimate of the material to be ingested by the body. By contrast, although the system in the Worthington et al. reference calculates a supplemental insulin dose, this calculation is not based upon an estimate of a material to be ingested by the body; instead, it is based on the patient's insulin sensitivity, as well as the difference between the patient's future and target blood glucose values. Additionally, although the system in the Worthington et al. reference calculates a carbohydrate supplement, this calculation is not an estimate of an amount of fluid to be infused; instead, it is a recommended number of grams of carbohydrates to be consumed by the patient to avoid developing hypoglycemia. Further, this calculation is not based upon an estimate of a material to be ingested by the body, as in the claimed embodiments; instead, it is based on the patient's carbohydrate value, which indicates the amount one gram of carbohydrates is expected to raise the patient's blood glucose value, as well as the difference between the patient's future and target blood glucose values. Therefore, it is respectfully submitted that claims 56-83 are not anticipated by the Worthington et al. reference.

For these reasons, withdrawal of the rejection of claims 56-83 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 84-95 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Worthington et al. in view of Welch et al. This rejection is respectfully traversed.

Claim 84 recites “calculating an estimate of the bolus amount of fluid to be infused into the body based upon the externally supplied values and the estimate of the material to be ingested by the body” (emphasis added). The applicants respectfully submit that the Worthington et al. and the Welch et al. references, either alone or in combination, do not disclose, teach, or suggest a method of estimating a bolus amount of fluid to be infused into the body, which calculates an estimate of an amount of fluid to be infused into the body based upon an estimate of a material to be ingested by the body, as recited in the claims.

Claims 84-95 are distinguishable over the Worthington et al. reference for the same reasons discussed above with respect to claims 56-83. The Welch et al. reference does not make up for the deficiencies of the Worthington et al. reference. The Welch et al. reference is directed to a network for managing multiple patient monitoring devices. However, the Welch et al. reference fails to disclose, teach, or suggest method of estimating a bolus amount of fluid to be infused into the body based upon an estimate of a material to be ingested by the body, as recited in the claims. Therefore, it is respectfully submitted that claims 84-95 are patentable over the Worthington et al. reference in view of the Welch et al. reference.

For these reasons, withdrawal of the rejection of claims 84-95 under 35 U.S.C. § 103(a) is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application and all the pending claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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